sleep questionnaire or on the derived MOS sleep scales. Significant improvement in the abatacept group compared to control on sleep adequacy, sleep disturbance, somnolence and both sleep problem indices I and II were found. For both studies, sleep quantity was not significantly difference between treatment groups, but optimal sleep significantly improved in the abatacept vs control group: ATTAIN (18% vs –12%, $p < 0.0001$) and AIM (16% vs 5%, $p = 0.0214$). **CONCLUSION:** Treatment with abatacept improves several different aspects of sleep in RA patients. In particular, sleep disturbance and sleep problems given by index II are reduced, and optimal sleep is improved.

PMS37

ASSESSING THE VALIDITY AND RELIABILITY OF A SIMPLE ACTIVITY PARTICIPATION MEASURE FOR RHEUMATOID ARTHRITIS CLINICAL TRIALS

Li T[1], Wells G[2], Tugwell P[2]
[1]Bristol-Myers Squibb, Princeton, NJ, USA, [2]University of Ottawa, Ottawa, ON, Canada

OBJECTIVE: To examine the validity, reliability, and sensitivity to change of a simple measure of activity participation for rheumatoid arthritis (RA) clinical trials. Joint damage from RA significantly limit patients' participation of daily work and non-work activities, however, few instruments were available to measure treatment effect on this aspect. **METHODS:** We measured activity participation in two randomized clinical trials of abatacept in active RA patients. Activity participation was assessed by two items: 1) the number of days in the past month a patient was unable to perform usual activities (paid or unpaid work, or any other daily activities), and 2) how often a patient was able to perform activities completely (scored 1–6, ranging from none to all of the time). For construct validity, correlations between the two activity items with clinical response and patient-reported outcomes were examined. Intraclass correlation coefficient (ICC) was used to assess test-retest reliability, and standardized effect sizes (SES) were calculated to evaluate sensitivity to change. **RESULTS:** In both studies at baseline, patients were limited for 15 days per month in usual activities and the score on activity completion was 3.7. After treatment, patients with EULAR clinical responses of good, moderate, none, gained back 11, 9, and 4 days of activity respectively, and patients who achieved minimal disease activity state gained 12 days vs. those who did not (7 days). Similar pattern was observed for the activity completion score. Moderate to strong correlations (0.5–0.6) between the two activity items with physical function, patient global, pain, and fatigue were found. The ICC for reliability was 0.6, and the SES was 0.5, indicating good response to change. **CONCLUSION:** The simple activity participation measure reflects true changes in patient clinical status and quality of life. It is valid, reliable, and sensitive to change, which suggests it is a suitable outcomes measure for clinical trials.

PMS38

ESTIMATING WORK PRODUCTIVITY: EFFECTS OF TRAMADOL EXTENDED-RELEASE TREATMENT

Benson C[1], Chang H[2], Lerner D[2], Rogers W[2], Mody S[1], Schein JR[1]
[1]Ortho-McNeil Janssen Scientific Affairs, LLC, Raritan, NJ, USA, [2]Tufts-New England Medical Center, Boston, MA, USA

OBJECTIVE: To estimate work productivity for patients treated with tramadol extended–release (ER) or placebo. **METHODS:** Intent-to-treat patients (18–65 years old) with chronic osteoarthritis pain from a 12-week, randomized, double-blind, placebo-controlled, fixed-dose study and treated with tramadol ER (100–400 mg) or placebo were compared. Work productivity was not assessed within the study, it was estimated using an imputation methodology. This imputation method cross-walks other health measures into Work Limitations Questionnaire (WLQ) scores. The WLQ is a validated questionnaire assessing health-related decrements in job performance and work productivity ("presenteeism"). According to this method, mean change in the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis total index scores were multiplied by the regression coefficients established for the WLQ and WOMAC. Productivity gains were translated to annual US dollars inflated to 2007. **RESULTS:** Baseline characteristics of tramadol ER and placebo groups were comparable. After 12 weeks of treatment, the tramadol ER treated patients significantly improved than placebo (WOMAC score of 23 vs. 16 points, $p = 0.002$). This 23 points improvement in WOMAC when imputed to WLQ translated into improvement of WLQ time management (8.15%), physical demands (11.78%), mental-interpersonal (5.99%), overall output demands (6.95%) and improvement in work productivity (1.96%). The improvement observed in the tramadol ER patients when aggregated to annual dollars per employee in 2007 ranged from [$1201–$7218], was numerically higher than placebo treated patients [$882–$5098]. Sensitivity analyses using other health-measures resulted in similar findings. **CONCLUSION:** Treatment with tramadol ER resulted in significant improvement in pain and physical function, when imputed to WLQ corresponded to productivity improvement.

PMS39

LOSS OF EMPLOYABLE LIFE-YEARS IN PATIENTS WITH RHEUMATOID ARTHRITIS: A PRELIMINARY ANALYSIS USING MARKOV MODEL

Han C[1], Tang B[2], Parasuraman S[3]
[1]Johnson & Johnson Pharmaceutical Services, LLC, Malvern, PA, USA, [2]Centocor, Inc, Horsham, PA, USA, [3]Johnson & Johnson Pharmaceutical Services, L.L.C, Malvern, PA, USA

OBJECTIVE: To estimate loss of employable life-years over time in patients with rheumatoid arthritis (RA). **METHODS:** We used a Markov model to estimate employable life-years using data from ASPIRE, a randomized clinical trial comparing the efficacy and safety of infliximab + methotrexate (MTX) (IFX group) and placebo + MTX (MTX group) among early RA patients. Employability state was defined as 'unemployable' if patients were unemployed and felt unable to work even if a job was available or 'employable' if patients were employed or felt well enough to work if a job were available. The one-year transition probability of employability was estimated using a logistic regression model, and loss of employable life-years was estimated using a two-state Markov model. **RESULTS:** For a patient at age 45 years, 31.4 % of female and 29.7% of male were unemployable using the regression model. For patients starting at age 45 and employable, the probability of remaining employable after one-year of treatment was 0.928 in males and 0.905 in females in the IFX group, and 0.899 in males and 0.867 in females in the MTX groups, respectively. For patients unemployable, the probability to be employable after one-year treatment was 0.481 in males and 0.405 in females in the IFX groups, and 0.390 in males and 0.319 in females in the MTX groups, respectively. In the Markov model, after 10 years at age 55, 18.5% of females and 14.1% of males in the IFX groups, and 30.7% of females and 24.2% of males in the MTX groups will be unemployable. On average, 0.99 employable life-years will be saved per patient over 10 years in IFX-treated patients compared to MTX-treated patients. **CONCLUSION:** This analysis presents a new method to estimate employable life-years using a Markov model, and